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08/302,241 09/08/94 WILSON

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| EXAMINER |
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18N2/0610

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| ART UNIT | PAPER NUMBER |
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1805

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DATE MAILED: 06/10/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 3/14/96 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire Three (3) month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- ☒ Notice of References Cited by Examiner, PTO-892.
- ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
- ☐ Notice of Art Cited by Applicant, PTO-1449.
- ☐ Notice of Informal Patent Application, PTO-152.
- ☐ Information on How to Effect Drawing Changes, PTO-1474.
- ☐

Part II SUMMARY OF ACTION

1. ☒ Claims 51-63 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 51-63 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

56-58 60-
Claims 51-55 and ~~59~~ 60-63 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 5,122,464. Although the conflicting claims are not identical, they are not patentably distinct from each other because the amplifiable expression vectors encoding the complete sequence of mammalian glutamine synthetase (GS) (optionally also containing a heterologous sequence encoding a desired protein and wherein said heterologous sequence is co-amplified with the GS gene) and host cells (i.e. CHO-K1 cells) transformed with said expression vectors are obvious in view of the claimed plasmids which include the GS minigene from pSVLGS.1 or the SV40-GS transcription unit from pSVLGS.1, wherein said pSVLGS.1 plasmid was designed to express and amplify the GS gene and heterologous gene operatively linked to said GS gene.

The claimed pSVLGS.tPA16 and pSVLGS.tPA17 vectors are obvious variants of the plasmids recited in U.S. Patent #5,122,464 since the claimed plasmids merely have the tPA gene inserted as the heterologous DNA which is to be co-expressed and amplified with the GS gene.

1. Claims 56-58 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 56 (and dependent claims) are vague in that applicants recite a host cell "...either completely lacking or reduced in GS activity..." The use of the term "reduced" renders the claims vague in that this term is subjective and could include a cell which produces 99.99% of normal GS activity; down to a cell

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producing 0.001% of normal GS activity, etc. If the host cell already produces an amount of GS sufficient to survive in a medium lacking glutamine, it is unclear what effect the transformation of the cell with the exogenous GS produces.

No claims are allowed.


Certain papers related to this application may be submitted to Art Unit 1805 by facsimile transmission. Papers should be faxed to Art Unit 1805 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (Nov. 16, 1993) and 1157 OG 94 (Dec. 28, 1993) (See 37 CFR 1.6(d)). The Art Unit 1805 fax number is (703) 308-0294. NOTE: If applicants do submit a paper by fax, the original signed copy should be retained by applicants or applicants' representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The Examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mindy Fleisher, can be reached on (703) 308-0407. The fax phone number for this Group is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

David Guzo
June 10, 1996


DAVID GUZO
PRIMARY EXAMINER
GROUP 1800